App. No. 10/522,887
Office Action Dated November 5, 2009

REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. The specification has been amended to address formal issues. No new matter has been added. Claims 17-20, 23-25 and 29-33 are pending.

Specification

The specification is objected to as introducing new matter. Applicants submit that the transgenic plants showing increased MnSOD activity as compared to non-transgenic plants in the presence of increased methylviologen concentration is supported by the original disclosure, for example, Fig. 1a, and therefore, the added material is not new matter (as is clear from originally submitted Fig. 1a, the transgenic plant Godawari 8 (shaded bars) showed an increase in MnSOD activity in the presence of higher concentrations of methylviologen (Paraquat) as compared to that of non-transgenic plant TP309 (blank bars)).

Withdrawal of the objection is respectfully requested.

Claim rejections - 35 U.S.C. § 112

Claims 24 and 33 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. To satisfy the deposit requirement, the Examiner is requiring a statement that the specific strains will be available to the public under the conditions specified in 37 CFR 1.808-1.809. A declaration by the Applicant satisfying the deposit requirements under 37 CFR §§ 1.803-1.808 is submitted herewith. Applicants respectfully request withdrawal of the enablement rejection.

Claim rejections - 35 U.S.C. § 103

Claims 17-20, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (Plant Science, 148: 131-139, 1999) in view of Bowler et al. (European Patent Publication No. EP 0359617A2), Nayak et al. (Proc. Natl. Acd. Sci, 94(6):2111-6), Verdaguer et al. (Plant Mol. Biol., 31(6):1129-39) and Davuluri et al. (Meeting Abstract, Plant Biology, 1999: 103). Applicants respectfully traverse the rejection.

The rejection refers to the first paragraph under the Discussion heading of Tanaka on page 136 and maintains that Tanaka does not indicate at page 136 that stable transformation of crop plants using the SOD is unpredictable. However, in the first paragraph under the Discussion heading, Tanaka refers to several groups (references 13-18) that use different

genomes (tobacco, alfalfa and cotton) and use SOD genes from a genus different from that of the host genomes, and indicates that their attempts have been successful to various degrees. The general understanding in the art of plant transformation is that unintended molecular effects can be expected when a crop plant is genetically transformed with genes from a genus or species different from that of the crop plant. Thus, given this understanding, Tanaka appears to suggest that the type of host genome used may be a factor in the degree of success in achieving stable transformation, and that experimentation would be necessary if a different host genome is used to transform with genes from a genus or species that is different from that of the host genome. Therefore, Applicants submit that Tanaka provides a reasonable basis to establish that even if stable transformation of a given host genome is shown to be obtainable for an SOD gene derived from a species that is different from that of the host genome, if a different host genome that is from a genus or species different from that of the given host genome is used in place of the given host genome, stable transformation of the different host genome being used is unpredictable, especially if the SOD gene is from a genus or species that is different from that of the respective host genomes. Applicants note that in method of claim 17, the genus of the genome that is transformed (*Oryza*) is different from that of the gene being used to stably transform the host (*Nicotiana*).

The rejection contends that it is inapposite that the gene used for transformation in Nayak requires substantial modification in order to be successfully expressed in transgenic plants since no such substantial gene modification appears to be required to express MnSOD genes in transgenic plants. However, Nayak fails to provide sufficient information to determine whether the reasons for substantial gene modifications were necessary due to the host genome, the gene being used for transformation, or a combination of factors. Nayak in fact clearly substantiates the general understanding in the art of plant transformation that unintended molecular effects can be expected when crop plants are genetically transformed with genes from a genus or species that is different from that of the crop plant. Factors that are responsible for such unpredictability include, for example, differences in the transgene integration site and locus configuration. Thus, Applicants submit that variation can be expected if a host genome that is part of an established system where the host genome is from a genus or species different from that of the gene used to transform the host genome, is replaced with a different host genome in the established system,

and the different host genome is from a genus or species that is different from that of the gene in the established system.

It is well established that indica and japonica can be clearly distinguished based on physiological and morphological traits including drought tolerance, potassium chlorate resistance, phenol reaction, plant height and leaf color. In fact, biochemical and molecular studies have shown that indica and japonica strains are closer in some characters or loci to different *O. rufipogon* strains than they are to each other (Hirano et al., J. Mol. Evol. 38:132-137 (1994)), indicating that indica and japonica are descended from ancestors of two different species. In particular, studies of the two genomes have shown that japonica strains are closely related to the perennial strains of one group, and the indica strains are closely related to another species, *O. rufipogon*, which is an annual strain (Chang et al., Mol. Biol. Evol. 20(1):67-75(2003)). Thus, given these differences between indica and japonica, there would not have been a reasonable expectation of success in replacing Tanaka's host genome, which is from a genus different from that of the MnSOD gene being used to transform the host, with that of Nayak's host genome, which also is from a different genus from that of Tanaka's MnSOD gene.

In addition, after stably transforming the calli, claim 17 requires regenerating the transformed calli into mature transgenic plants of the indica rice variety. Applicants submit that to successfully apply the tissue culture technique to crop breeding, callus growth and plant regeneration potential of each crop must be determined. Even within the indica rice group, there are significant variations in the *in vitro* cultures response among different genotypes (Ozawa & Komamine, 1989; Peng & Hodes, 1989). Efficient regeneration systems and parameters for culture conditions need to be identified and standardized for the indica varieties. Tanaka, Nayak, Bowler and Verdaguer fail to provide any reason to expect that mature transgenic plants of the indica rice variety could be achieved after stably transforming the rice calli as required by claim 17. Accordingly, claim 17 and its dependent claims are patentable over the references.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

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In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully submitted,

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Dated: February 5, 2010

By: _____
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